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Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: the CLEO trial

Submission date 15/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/01/2010	**Overall study status** Completed	
Last Edited 29/12/2020	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
22/2006

Study information

Scientific Title
Short versus standard treatment with pegylated interferon alfa-2a plus ribavirin in patients with hepatitis C virus genotype 2 or 3: a randomised controlled trial

Acronym
Study short treatment (reduction duration)

Study objectives
To verify if a 12-week regimen of a combination of pegylated interferon alfa-2a and ribavirin was as efficacious as a 24-week regimen in patients with hepatitis C virus (HCV) genotype 2 or 3.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Azienda Ospedaliera San Camillo Forlanini approved in 2005 (ref: 489)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic hepatitis C genotype 2 and 3

Interventions
Patients fulfilling the selection criteria received in an open-label fashion pegylated interferon alfa-2a at a dose of 180 µg subcutaneously once weekly and oral ribavirin, at a dosage of 1000 mg/day (for those with a weight of less than 75 kg) or 1200 mg/day (for those with a weight of greater than or equal to 75 kg). Patients with rapid virological response (RVR) defined as HCVRNA less than 50 IU/ml after 4 weeks of treatment, were randomly assigned in a 1:1 ratio to receive a treatment either for 12 weeks. Patients without RVR were treated for a standard period of 24 weeks.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pegylated interferon alfa-2a, ribavirin

Primary outcome measure
Sustained virological response (SVR) which was defined as undetectable plasma HCVRNA (less than 50 IU/ml) 24 weeks after the end of treatment.

Secondary outcome measures
1. Virological response rates (HCVRNA negative in serum with a detection limit of 50 IU/ml) at the end of therapy
2. Severity and frequency of adverse events

Overall study start date
10/05/2006

Completion date
10/01/2008

Eligibility

Key inclusion criteria
1. HCV ribonucleic acid (RNA) positive
2. HCV genotype 2 or 3
3. Elevated alanine aminotransferase (greater than 40 IU/L) at least 8 months prior to study entry
4. Histologically proven chronic HCV hepatitis
5. Naive to treatment
6. Aged 20 - 68 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Total final enrolment
210

Key exclusion criteria

1. Known to have injected drugs or alcohol abuse (greater than 40 g ethanol/day) within the 6 months prior to study entry
2. Poorly controlled psychiatric illness
3. Decompensated cirrhosis
4. Positive for human immunodeficiency antibody virus or positive for hepatitis B surface antigen
5. Pregnancy, lactation
6. Impaired renal function
7. Other concurrent medical conditions of the liver different from HCV infection

Date of first enrolment
10/05/2006

Date of final enrolment
10/01/2008

Locations

Countries of recruitment
Italy

Study participating centre
Via Terni 97 (private address)
Rome
Italy
00182

Sponsor information

Organisation
Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

Sponsor details
Via di Villa Troili 6
Rome
Italy
00163

Sponsor type
Hospital/treatment centre

Website
http://www.clubepatologiospedalieri.org/online/

Funder(s)

Funder type
Research organisation

Funder Name
Club Hepatology Hospital (Club Epatologi Ospedalieri [CLEO]) Group (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/02/2010	29/12/2020	Yes	No